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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,437	09/08/2003	Wen-Ghih Tsang	021164-000310US	4741

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,437

Applicant(s)

TSANG ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 35-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/04;3/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 6 – 20, and the elected species of an antibody that binds to the CD56 protein, in the reply filed on December 27, 2005 is acknowledged. The traversal is on the ground(s) that the groups are related and there is not a serious search burden. This is found persuasive in part. Specifically, to Group III. Since the groups were searchable without serious burden, claims 21 – 34 were rejoined with the elected group II. Regarding Groups I, IV and V, the argument is not found persuasive because while the groups are related, the search is not coextensive. Thus a reference that would anticipate or make obvious one group would not necessarily anticipate or even make obvious another.

The requirement is still deemed proper between groups I, IV and V, and is therefore made FINAL.

Claims 1 – 55 are pending, claims 1 – 5 and 35 – 55 are withdrawn as being drawn to non-elected subject matter; claims 6 – 34 have been examined on the merits, insofar as they read on the elected species of an antibody that binds to the CD56 protein.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 6 – 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, 34 and their dependents are drawn to a method for obtaining a culture of propagating pancreatic cells, however are rendered vague and indefinite because it is unclear which cell population is being obtained to create the propagating pancreatic cells, the cells that do bind to CD56 or the cells that do not bind to CD56.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 6 – 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fung et al. (US 6326201) in view of Shipley et al. (1997).

Applicant claims a method for obtaining a culture of propagating pancreatic cells, comprising isolating pancreatic cells from a pancreas, contacting the cells with a CD56 binding reagent, selecting the cells that bind to CD56, and separating the cells that do not bind to the CD56, to obtaining a culture of propagating pancreatic cells. The binding reagent is labeled; the cells are selected by FAS or panning; the binding reagent is an antibody that binds to the CD56 protein; the pancreas is human; the cells are further differentiated into an aggregate of insulin producing cells wherein differentiation comprises culturing the cells on plates coated with collagen IV. The media comprises a differentiation factor selected from hepatocyte growth factor (HGF), keratinocyte growth factor or exendin-4, specifically hepatocyte growth factor.

Fung teaches a method for obtaining a culture of pancreatic cells (abstract) the method comprising obtaining pancreas cells, culturing the cells, isolating viable cells, culturing the cells and differentiating the cells (col.10-11). The cells are obtained from human pancreas (col.11), the cells are selected by FAS or panning (col.14,19-20), the cells are differentiated into aggregates of insulin producing cells (col.12), the cells are differentiated with HGF (col.15), and/or are cultured with collagen IV (col.17). Fung teaches the cells are isolated using labeled antibodies (col.19-20).

Fung does not teach the method wherein the labeled antibody is CD56. However, at the time of the claimed invention, it was known in the art that pancreatic cells express CD56. In support, Shipley teaches CD56 is expressed in pancreatic islets, and that the marker can be used to isolate pancreatic cells (abstract, p.87,88). Thus, at the time of the claimed invention, it would

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have been obvious to one of ordinary skill in the art to utilize CD56 as the labeled binding reagent of Fung, since it was a known marker of pancreatic cells, as evidenced by Shipley. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Shipley to use CD56 as the labeled binding reagent of Fung with a reasonable expectation for successfully obtaining a culture of propagating pancreatic cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 18, 2006
AU 1651


RUTH A. DAVIS
PATENT EXAMINER